

**Summary of the
On-Site Assessment Committee Meeting
NELAC Iii
February 3, 1997**

The National Environmental Laboratory Accreditation Conference (NELAC) On-Site Assessment Committee met from 10:30 a.m to 3:15 p.m. Eastern Standard Time (EST) on Monday, February 3, 1997. The meeting was led by Mr. Gary Bennett, Chair, USEPA Region 4. A list of action items is given in Attachment A. A list of Committee members is given in Attachment B.

INTRODUCTION

The purpose of the meeting was to continue to review revisions to Chapter 3, "On-Site Assessment." The following items were discussed according to the prepared agenda:

- The confidential business information (CBI) section of the document (Section 3.4.5), and
- Comments on the assessor training course and standards.

**SYSTEMATIC REVIEW OF CHAPTER 3, SECTION 3.4.5
3.4.5 -- Confidential Business Information (CBI) Considerations**

The following issues were raised:

1. Removal of CBI documents/copies from the facility's premises by a NELAC assessor was discussed. It was noted that this section conflicts with Chapter 4, Section 4.1.2(c) (under "Announced Assessments") regarding the role of the lead assessor in removing CBI documents from the laboratory.
2. It was recommended that the statements about the copying of information and the role of the lead assessor in this regard be reviewed by U.S. Environmental Protection Agency (USEPA) legal counsel.
3. Assessors need the ability to obtain hard copies of reports and data.
4. The elements of the National Environmental Laboratory Accreditation Program (NELAP) assessment confidentiality notice should be delineated in Chapter 3. The Committee should check whether this is covered in Chapter 4 ("Accreditation Process").
5. Implementation issues (who? how?) of issuing CBI clearance to assessors was discussed.

Considerable discussion ensued on the appropriate course for determination of what precisely is defined as CBI. Concerns were expressed among private-sector representatives that assessors may give CBI to an enforcement arm of an agency.

It was emphasized that the State's enforcement authority cannot be limited by NELAC standards. It was noted that Chapter 6, Section 6.3.3 (pp.18 of 35, nos. 16-18), deals with which authorities have purview over these issues.

Numerous suggestions for changes to this section were submitted by individuals and State agencies. The Committee is reviewing these suggestions for possible incorporation into the CBI section of the chapter. The Chair encouraged all participants to submit any further questions or comments. Such comments will be deliberated by the Committee, and these deliberations will be reflected in the minutes of future Committee meetings.

ASSESSOR TRAINING COURSE/MANUAL, SECTIONS 3.2.1, 3.2.2

The manual should offer specific suggestions for what an assessor can and cannot do legally.

Mr. Steve Baker, Chair of the training course subcommittee, is working on assessor training programs.

Reciprocity with other training bodies is being considered. Once NELAP is developed, consideration of other programs' approval may be considered on a case-by-case basis.

Additional questions and recommendations were raised:

1. Other training program models (e.g., American Association for Laboratory Accreditation [A2LA], Food and Drug Administration [FDA] Lab Evaluation for Dairy Labs, Association of State and Territorial Public Health Laboratory Directors [ASTPHLD]) are being considered.
2. Reciprocity with other organizations/authorities is being studied.
3. ISO guidelines (e.g., 10011) will be followed where appropriate.
4. Develop a draft assessor training program, with the goal of doing so before the Third NELAC Annual Meeting.
5. The Assessor Training Manual should be available before the Third NELAC Annual Meeting.
6. Should current assessors be "grandfathered in"? This concept was strongly favored by most participants (e.g., representatives from Kansas, Oregon, Wisconsin, Maryland, North Carolina, Illinois, Ohio and New Hampshire). Knowledge of ISO Guide 25, which addresses the general technical competence of laboratories, would be a requirement of "grandfathering in". This is covered in Chapter 5 of the NELAC document. A specific time period (e.g., 3 years) to complete new training and become qualified might be specified. The legal implications of assessors (who had been in the field) failing the training course/test should be considered.

“Grandfathered” assessors would still need special training to ensure that the required assessor skills were not compromised. Points to consider in “grandfathering” include the effects on States' employment practices and statutes.

Chapter 6 ("Accreditation Authority") addresses much of this area.

7. A proficiency test, instead of a training course, could be required for qualification. Consideration should be given to other formats for facilitating training (e.g., video) within the States.
8. A baseline course covering the NELAC standards (Chapter 5) would be the base requirement. In the future, methods of training for specialized areas could be left to the States, other associations involved in this field, or USEPA. This training would be subject to oversight by NELAP.

CLOSING COMMENTS

The Chair solicited specific comments on all sections of the chapter, noting that all sections of the chapter, except Section 3.4.5, have been approved.

Comments in the discussion included:

- Sections 3.3.1/3.3.2 --The meaning of "comprehensive" will be clarified. The Committee's intent was to assess general requirements and specific fields of testing on a minimum 2-year frequency. Note that the accrediting authority determines the follow-up/frequency of assessment.
- Section 3.1 -- Reconsider the use of the word "judge" in the last sentence. Also, in Sections 3.1, 3.6.1, 3.6.4, and 3.7.2, language on health and safety should be stricken. The Committee believes that Section 1.9.3 addresses this issue sufficiently.
- Section 4.1.2 should be moved into Chapter 3.
- “Assessment may consist of any and all of the categories” language presented in Section 4.1.4(d) should resemble language in Section 3.4.2, requiring all of the categories.
- On-site assessment checklists have yet to be developed. The On-Site Assessment Committee was waiting for the Program Policy and Structure Committee to delineate the approach to accreditation (i.e., field of testing). Since this approach has been specified, the development of checklists can proceed.
- The intent of Section 3.5.3(p) regarding internal audits and need for review by the NELAC assessor (details or summary) was discussed. Note that Section 5.5.3 covers this; it may be possible to cross-reference Section 5.5.3 here.

- How information gathered during assessment should be used can be addressed during assessor training.
- A good model may be the good laboratory practice (GLP) quality assurance (QA) unit statement on internal audits.
- Clarification of Section 3.5.3(q) is provided by Section 5.5.3.2; insert a cross-reference. Also, consider changing “report” in Section 3.5.3(q) to “records” (throughout Section 3.5.3).
- Clarify Section 3.5.6 language for the time frame necessary to implement and document corrective actions. Reword the sentence. In sentence 2, change “and address” to “to address.” Section 4.1.4 is consistent with Section 3.5.6.
- Section 3.5.7 -- Clarify the decertification process when public welfare is compromised. See also Section 4.4.3 (“Suspension”).
- Note that Chapter 4 is simply a synopsis of other sections. When the rest of the document is complete, Chapter 4 will be revised to reflect the language in other sections.
- Section 3.5.3 (“Records review”) needs clarification regarding what is reviewed during the on-site visit versus what is reviewed prior to the site visit.

CONCLUSION

The Chair concluded the Committee meeting, noting that specific suggestions raised at this Second NELAC Interim Meeting would be considered by the Committee for inclusion within the document.

ACTION ITEMS
On-Site Assessment Committee Meeting
February 3, 1997

Item No.	ACTION	Date Completed
1	Summarize input on Section 3.4.5 and determine final language with a conference call.	
2	Gary Bennett will have USEPA legal staff review the CBI section: A) Does an assessor have the right to copy and remove CBI from a lab? B) Will the CBI section cause problems?	
3	Discuss the position on “grandfathering” of assessors during the next conference call.	
4	Gary Bennett will check with Steve Baker and the training program subcommittee -- need draft of product by June 1, 1997.	
5	Rosanna Buhl will submit language from GLP regarding CBI.	
6	Gary Bennett will change “reports” to “records” in Section 3.5.3(q).	

LIST OF COMMITTEE PARTICIPANTS
On-Site Assessment Committee Meeting
February 3, 1997

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